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EXAMINER

WOITACHEL JOSEPH T

ARTICLE PAPER NUMBER

1632

DATE MAILED 03 27 2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,110

Applicant(s)

Pasricha et al.

Examiner

Joseph Weitach

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 3, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1632

DETAILED ACTION

This application filed April 12, 2001, claims benefit to provisional applications 60/198,806, filed May 13, 2000, and 60/232,301, filed September 12, 2000.

Applicants amendment filed January 3, 2003, paper number 15, has been received and entered. Claims 1-17 have canceled. Claims 18-20 have been amended. Claims 21-43 have been added. Claims 18-43 are pending.

Election/Restriction

As stated in the previous office action Groups I and II were rejoined because both groups could be examined without serious burden as they are drawn to a method for the treatment of the elected species of a degenerative disorder. Further, the election of species was maintained because the search and specific considerations for each disorder would not be co-extensive, and would constitute an undue burden.

Newly added claims 21-34 are drawn to a method of repopulating cells within a gastrointestinal organ and are broader than the original claims for treating a degenerative disorder. Though the claims only recite a method of 'repopulating' not a method of treatment, the claims imply that cells are lost or lacking in the subject, thus there is a need to repopulate the cells. Further, why the cells are lacking is not recited, both the methods of claims 21-34 and the previous claims directed to the elected invention of treating a degenerative disorder were

Art Unit: 1632

generally drawn to providing a new source of cells to a subject who had lost cells. Additionally, it is noted that methods of repopulating dependent claims recite that the cells are administered to subjects with specific disorders (see claim 27). Though claims 21-34 are broader as they are drawn to simply providing cells to a subject, they will be examined to the extent they encompass the elected invention of a method for the treatment of a degenerative disorder.

Newly added claims 35-40 are drawn to a method of providing a neurotransmitter within the gastrointestinal tract and newly added claims 41-43 are drawn to treating a disorder of the enteric nervous system, and though no specific degenerative disorder is set forth which would require these specific applications or treatment, they will be examined to the extent they encompass the elected invention of a method for the treatment of a degenerative disorder. Specifically, claims 35-40 will be examined to the extent that providing a neurotransmitter would be a treatment of degenerative disorder, and claims 41-43 will be examined to the extent that implanting cells into the intestine will treat a degenerative disorder, in particular where in the cells provide nitric oxide (claim 42).

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1632

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 18-43 are pending and currently under examination as they are drawn to the elected invention of a method for the treatment of a degenerative disorder.

Response to Amendment

The declaration of Pankaj Jay Pasricha and Maria-Adelaide Micci under 37 CFR 1.132 filed January 3, 2003, paper number 14, is insufficient to overcome the rejection of claims 18-20 and newly added claims 21-43 based upon 35 USC 112, first paragraph as set forth in the last Office action. The declaration will be discussed in detail below as it pertains to the specific basis of the rejection.

Specification

The disclosure objected to because the disclosure contains an embedded hyperlink and/or other form of browser-executable code is withdrawn.

Applicants point out that the website addresses pointed to by Examiner are not complete and would not be active. Examiner agrees that the recitations present in the specification are not

Art Unit: 1632

active hyperlinks. Further, the information which may be provided at these sites are generally summarized in the preceding passage of the disclosure. Thus, sometime in the future if the information may not be obtained at these sites or if the information changes, the general reliance of the information at these websites would be understood given the context of the disclosure.

Claim Objections

Newly added claims 21-26, 28-43 are objected to because of the following informalities:

The election of species was made to a degenerative disorder, however the claims broadly encompass any disorder. The claims should be amended to reflect the elected invention.

Applicants note that MPEP 809.02(a) states that claims will be limited to a single species if no generic claim is found allowable and that it is inappropriate at this time to require amendment to the claims.

First, Examiner agrees that claims 18-20 were not subject to the species election and are drawn to the elected invention previously set forth as group II. However, claims 21-43 are broader than the claims previously set forth as they are drawn to treatment of a degenerative disorder. No generic claim has been found allowable, accordingly the claims should be amended to reflect the elected invention. Again, as noted in the section of Election/Restriction, claims 21-43 are broader and different than the methods previously set forth in group I, original claims 1-17, and should be amended to reflect the elected invention.

Art Unit: 1632

Claim Rejections - 35 USC § 112

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case the embodiment of expressing the specific neurotransmitter is considered new matter. It is noted literal support for the term 'substance P' is found in the specification at page 11, lines 10-11, however this portion of the specification describes antibodies and possible antigens for staining cells. The specification does not support providing the specific neurotransmitter 'substance P' by transplanting cells for any reason or in any context of treatment.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claim 37 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue

Art Unit: 1632

arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claims 18-20 stand rejected and new added claims 21-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

With respect to claims 18-20, Applicants summarize the nature of the invention and amendments to the claims encompass the use of neuronal stem cells into the pancreas of the subject. Applicants argue that the specification provides adequate guidance to practice the method encompassed by claims 18-20 (pages 7-8). Specifically, Applicants argue that neuronal stem cells are capable of differentiating into particular cells found in the hematopoietic, skeletal, liver and intestinal lineages (page 8). Applicants compare the neuronal stem cell to those

Art Unit: 1632

disclosed and isolated from the pancreas and liver and argue that the neuronal stem cell would be expected to have the same capacity to differentiate as the liver and pancreatic stem cells (pages 8-9). Additionally, Applicants argue that avoiding acute rejection xenotransplantation can be accomplished by immunosuppressive techniques generally disclosed in the specification or known in the art (page 10). Further, Applicants note that to further address the issue of xenotransplantation supplementary evidence has been provided in the declaration of Pasricha and Micci filed under 37 CFR 1.132 (pages 10-12 and declaration-paper number 14).

With respect to claims 21-43, Applicants summarize the nature of the invention encompassed by the newly added claims, and as above argue that the specification provides adequate guidance to practice the method encompassed by claims 21-43 (pages 12-15). In particular, Applicants note that *in vitro* the neuronal stem cells produce express nNOS and produce NO and substance P (pages 12-13 and supported by evidence in declaration-paper number 14). Additionally, Applicants argue that providing neuronal stem cells to the pylorus in mice in which the allele for nNOS has been deleted results in increased gastric emptying demonstrating the beneficial and functional effect of transplanting neuronal stem cells (pages 14-15 and Exhibit D of declaration). See Applicants' amendment, pages 7-16. Applicants' arguments have been fully considered but not found persuasive.

First, with respect to all claims, it is noted that the specification recites only general methodology and provides no means to avoid the hosts immune system which is the major source for graft rejection in xenotransplantation. Further, the evidence provided in the declaration does

Art Unit: 1632

not address the problems of xenotransplantation in that cells for transplantation are isolated from a mouse and returned to a mouse, and the issue of cross species transplantation is not addressed. As set forth in the previous office action, Mandel teaches that conventional methods known in the art are not the "usually adequate for control of allograft rejection generally does not prevent xenograft rejection" (page 155; abstract). Applicants' arguments that the evidence provided in the declaration address the issue of xenotransplantation is not convincing because relevant evidence is not presented. Further, the present specification only provides general guidance for avoiding graft rejection relying on the art for the specific guidance to affect immunosuppression, therefore the disclosure is subject the same limitations recognized in the art. It is maintained that the present specification fails to provide the necessary guidance to practice the invention wherein cells from different species are used.

More specifically with respect to claims 18-20 the previous office action noted that Taniguchi *et al.* teach that the host immune response also affected the ability to administer cell therapy even when the cells were encapsulated. In the example to treat hyperglycemia in diabetic mice, encapsulated cells induced an inflammatory response by virtue of the human insulin produced (page 44; bottom of first column). Thus, even if major surface antigens are avoided, the molecules produced by the cell prevent the effective expression of a secreted protein. In this case, enhanced levels of insulin expressed by a cell from a different species would not be produced because of their antigenicity in a subject. Additionally, with respect to providing transplantation of single cells it was noted that the art teaches that the success rate of isolated

Art Unit: 1632

cell allograft is poor and "the reasons for this are not fully understood" (page 155-56; bridging paragraph). The specification provides no specific guidance to overcome this art recognized limitation for the transplantation of cells to the pancreas. Finally, stem cells isolated from different tissues provide a unique cell with different inherent properties. Examiner acknowledges that the art has taught that pancreatic and liver stem cells have been isolated, however there is no nexus between the property demonstrated with these cells and the properties of neuronal stem cells disclosed in the instant specification. The evidence presented in the specification and the declaration provide no basis that neuronal cells have the capacity to differentiate into cells which produce insulin. Further, even if the neuronal cells were demonstrated to have the capacity to differentiate into beta cells, there is evidence that they would behave any differently than endogenous beta cells in the subject. More specifically, by providing a cell to subject which differentiates into a cell which produces insulin, one would expect the cell to be regulated like an endogenous cell and produce insulin as required in the subject, and there would be no 'enhanced levels of insulin' only a normal level of regulated insulin production.

With respect to newly added claims 21-43, it is noted that the claims are only considered to the extent that they encompass the elected invention of treating a degenerative disorder (see discussion in Election/Restriction above). Initially, for claims 21-34 and in part claims 41-43 the only described purpose for repopulating cells provided by the specification would to affect treatment to a subject. There is no guidance for providing cells to a normal subject who maintain a normal number of cells. Further, with respect to claims 35-43 the only describe purpose for

Art Unit: 1632

delivering a neurotransmitter or nitric oxide to a gastrointestinal tract is to affect some disorder in a subject. The specification provides several disorders which are associated with the loss of neuronal cells in the gastrointestinal tract of a subject, however there is no nexus that neuronal stem cells would replace these cells. Further, in general and with respect to the specific disorders set forth in claim 27, there is no indication that providing a neuronal cell will provide any form of treatment to a subject. The specification is silent with respect to specific guidance to the number of neuronal stem cells to transplant which could then differentiate and subsequently provide any therapeutic affect. Examiner notes evidence provided in Exhibit D of the declaration and that these experiments demonstrate that providing NOS can alleviate symptoms caused by the lack of NOS, however the specification is silent with respect to degenerative disorders in which lack of NOS is cause of the disorder or would be ameliorated by its administration. Further, it is noted that the evidence indicates that substance P is secreted by the differentiated neuronal stem cells *in vitro*, however even if this differentiation was recapitulated *in vivo* the specification is silent to why or how the artisan would use this observation.

As noted in the previous office action the claims are drawn broadly to a method of treating a degenerative disorder comprising implanting stem cells or progeny thereof into a gastrointestinal organ. The specification teaches that degenerative disorders is considered broadly to encompass specific diseases associated with the gastrointestinal tract as well as a variety of disorders not traditionally considered gastrointestinal disorders but related to organs associated with the gastrointestinal organs (page 5; lines 15-27). Encompassed within this broad

Art Unit: 1632

definition diseases such as diabetes, cirrhosis of the liver, as well as other diseases which are associated with the destruction of a particular organ could be treated by the instantly claimed methods. It is noted that the methods simply recite implanting stem cells into a subject, though dependent claims recite specific routes of delivery and delivery to particular organs. The specification provides no working example of the instantly claimed invention as it is drawn to providing treatment or the production of insulin. The only working example presented in the disclosure describes the isolation of a neural stem cell from fetal tissue and transplantation of said cells into the pylorus of the gastrointestinal tract of a mouse. In the working example the neuronal cells differentiate into nitrogenic neurons (page 14). The specification provides only a general summary of a broad range of potential disorders to be treated and a description of sources of stem cells known in the art at the time of filing.

The specification is silent with respect to specific methodology for cell transplantation and provides no guidance for specific treatments of specific disorders except to for the general administration of stem cells for affecting any desired treatment. As discussed above the specification fails to provide a reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent application (27 USPQ2d 1662 *Ex parte Maizel*). Further, the specification fails to provide the necessary guidance to overcome even the specific art recognized limitations for providing cells which produce insulin. The breadth of the claims is large encompassing any type of stem cell, any means of delivery and affecting treatment for any type of disorder. In view of the quantity of experimentation necessary

Art Unit: 1632

to determine the parameters listed above for each disorder and/or cell type, the lack of direction or guidance provided by the specification, the absence of working examples for the demonstration or correlation to affect any treatment, and the general unpredictable state of the art with respect to affecting any treatment, it would have required undue experimentation for one skilled in the art to make and/or use the claimed inventions as broadly claimed. The specification provides insufficient guidance to teach how to engineer the delivery of insulin to any therapeutic effect in any of the methods proposed.

The high degree of unpredictability associated with a single claimed method underscores the need to provide teachings in the specification that would provide the artisan with specific methodology to practice the full breadth of the claimed invention. In the instant case, the specification does not provide any specific guidance for any specific disease for a therapeutic benefit by a cell based therapy. Further, the specification fails to provide any correlation between routes of delivery (e.g. intratumoral, intravenous etc.), implantation into cells, dosage amounts/frequencies, and specific forms of diseases treatable by the cells comprising such as those disclosed in the instant specification. Without such guidance in the specification the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan. (See *Genentech inc v. Novo Nordisk A/S* 42 USPQ2d 1001, at 1005).

Art Unit: 1632

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the metes and bounds of the claims are unclear in the recitation of 'neuronal stem cells and/or progeny thereof' because what is encompassed by a neuronal stem cell is not clearly defined or set forth. Previously the claims were directed to stem cells and progeny thereof, however the amendment is now directed to neuronal stem cells which could have been progeny of stem cells. For example, claim 18 indicates that the cell is totipotent, however if cell is totipotent would it be considered a neuronal stem cell? It is unclear if neuronal stem cell is considered a limitation from where the cell is isolated or the capacity of the particular stem cell to differentiate. For example, would a multipotent stem cell be considered a neuronal stem cell because it has the same capacity to differentiate into the same progeny of cell types? Further, claim 20 is unclear because there is insufficient antecedent basis for 'the cells' and it is unclear to what 'cells', neuronal stem cell or progeny, that 'the cells' refers.

Art Unit: 1632

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the metes and bonds of the term 'administering the cells locally' is not clearly defined. The specification does not specifically define the term 'locally' or describe the methods encompassed by local delivery of cells, and it is unclear if the term refers to delivery of cells to where the cells are lacking and need to be repopulated, or more generally to an area that is comprised by the target tissue/organ as a whole. More clearly setting forth how or where the cells are administered would obviate the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 22, 28, 29, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Luo *et al.* (Xenotransplantation 1998 Aug;5(3):197-206).

Newly added claims 21 is drawn to a method of repopulating tissues with a gastrointestinal organ comprising implanting stem cells or progeny thereof into the gastrointestinal organ. There is no limitation on the nature of progeny or how the cells are provided, and thus claims 21, 22, 28, 29, 32 broadly encompasses transplanting a tissue. Further,

Art Unit: 1632

claims 28 and 29 indicate that the solid gastrointestinal organ can be the liver. At the time of filing, Luo *et al.* teach a method of liver transplantation. By providing liver cells in the method Luo *et al.* teach a method of repopulating cells of a gastrointestinal organ.

Claims 21, 22, 25, 26, 30, 31, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller *et al.* (J Invest Surg 1997 Nov-Dec;10(6):375-8).

Newly added claims 21 is drawn to a method of repopulating tissues with a gastrointestinal organ comprising implanting stem cells or progeny thereof into the gastrointestinal organ. There is no limitation on the nature of progeny or how the cells are provided, and thus claims 21, 22, 25, 26, 30, 31, 32 broadly encompasses transplanting a tissue. Further, claims 28 and 29 indicate that the hollow gastrointestinal organ can be the bowel or intestine. At the time of filing, Keller *et al.* teach a method of intestine transplantation. By providing the intestine to a subject in the method Keller *et al.* teach a method of repopulating cells of a gastrointestinal organ.

Conclusion

No claim is allowed.

Claims 21, 22, 25, 26, 28, 29, 30, 31, 32 are anticipated by the art of record. The remaining claims are free of the art of record because the art fails to teach and enable the breadth of the instantly claimed method. However, the claims are subject to other rejections.

Art Unit: 1632

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630